K011226

JUN 2 5 2001

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3544

Contact Person: Kay A. Taylor

Date Prepared: April 18, 2001

Device Name

Proprietary name: Calibrator for Automated Systems (C.f.a.s.) Proteins

Common name: C.f.a.s. Proteins

Classification name: Calibrator, Multi-analyte mixture

Device Description

The Calibrator for Automated Systems (C.f.a.s.) consists of liquid human serum with biological materials added as required to obtain desired component levels. Values for constituent analytes are provided in product labeling.

510(k) Summary, Continued

Intended use

For use in the calibration of quantitative Roche immunoturbidmetric methods on clinical chemistry analyzers.

Substantial Equivalence

The Calibrator for Automated Systems (C.f.a.s.) Proteins is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Diagnostic Calibrator for Automated Systems (C.f.a.s.) (K990460). The intended use of both devices is the establishment of calibration curves for their respective test systems.

Substantial equivalence - similarities

The following table compares the Calibrator for Automated Systems (C.f.a.s.) Proteins with the predicate device.

Feature	C.f.a.s. Proteins	C.f.a.s. (Predicate Device)
Intended Use	For use in the calibration of quantitative Roche immunoturbidmetric methods on clinical chemistry analyzers.	For use as a calibrator of clinical chemistry assays for automated analytical procedures.
Format	Pooled human sera with constituents added as required to obtain component levels.	Pooled human sera with constituents added as required to obtain desired component levels.
Stability	• Stable at 2-8°C until expiration date. • Stable for 1 month at 2-8°C, with exceptions noted in labeling.	• Stable at 2-8°C until expiration date. • Stable for 2 days when constituted, stoppered, protected from light and stored at 2-8°C, with exceptions noted in labeling.
Levels	Single Level	Single Level

Substantial equivalence – differences

Comparison of proposed Calibrator for Automated Systems (C.f.a.s.) Proteins and predicate device.

Feature	C.f.a.s. Proteins	C.f.a.s. (Predicate Device)
Matrix	Liquid- ready to use	Lypophilized

Constituent Analytes

C.f.a.s. Proteins	C.f.a.s. (Predicate Device)
α1-antitrypsin	Acid Phosphatase
C3c	Alkaline Phosphatase
C4	Alanine Aminotransferase
Ceruloplasmin	α-Amylase
C-Reactive Protein (Latex)	Aspartate Aminotransferase
Haptoglobin	Cholinesterase
Prealbumin	Creatine Kinase
Transferrin	γ-Glutamyltransferase
	Lactate Dehydrogenase
	Lipase
	Albumin
	Bilirubin (Direct)
	Bilirubin (Total)
	Calcium
	Cholesterol
	Creatinine
	Glucose
	Iron
	Magnesium
	Phosphorus (Inorganic)
	Total Protein
	Triglycerides
	Uric Acid
	Urea (BUN)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2001

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) Number: K011226
Trade/Device Name: Calibrator for Automated Systems (C.f.a.s.) Proteins
Regulation Number: 862.1150
Regulatory Class: II
Product Code: JIX
Dated: April 18, 2001
Received: April 20, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

K011226

510(k) Number (if known): N/A

Device Name: Calibrator for Automated Systems (C.f.a.s.) Proteins

Indications For Use:

For use in the calibration of quantitative Roche immunoturbidmetric methods on clinical chemistry analyzers.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011226